Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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Safer use of medical products through timely and effective risk communication to stakeholders

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National Coordination Centre - Pharmacovigilance Programme of India

A WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services

Indian Pharmacopoeia Commission

Ministry of Health & Family Welfare, Government of India

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MESSAGE

Message from the Desk of Secretary-cum-Scientific Director IPC

Dear Readers,

I am privileged to release the Pharmacovigilance Programme of India (PvPI) Newsletter Volume 15, Issue 4 for the index period of October to December, 2025 on the theme 'Risk Communication for Patient Safety'

30 Adverse Drug Reaction Monitoring Centres (AMCs) have been enrolled under PvPI in this quarter and total number of AMCs are 1150 across the country. A total of 10.64 Lakh Individual Case Safety Reports (ICSRs) has been reported to PvPI. The PvPI is regularly sensitizing its stakeholders about the pharmacovigilance and reporting of Adverse Events through Awareness Programmes, Trainings, Workshops, Skill Development Programmes, Continuing Medical Education (CME) etc. The PvPI has organized a total of 386 training programmes and trained a total of 22289 participants in the area of pharmacovigilance in this quarter.

The NCC-PvPI, IPC has issued a total of 183 drug safety alerts so far for the sensitization of healthcare professionals and reporting of such adverse drug reactions to PvPI, if encountered with the use of such drugs.

At global level, the NCC-PvPI, IPC being a World Health Organization-Collaborative Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services is regularly sharing the latest information to the SEARN Countries on safety and regulatory actions of medical products taken by the CDSCO based on PvPI recommendations

As a team, we will continue to work to improve patient safety. I congratulate the PvPI team, AMCs, subject experts and other stakeholders for their ceaseless efforts, cooperation and contribution in strengthening the pharmacovigilance system in India.

(Dr. V. Kalaiselvan)
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
(Ministry of Health & Family Welfare,
Government of India)
Ghaziabad - 201002

Risk Communication for Patient Safety

Risk communication to stakeholders in a timely and transparent manner is a vital component of pharmacovigilance and plays a key role in ensuring patient safety. Effective communication of drug safety information helps healthcare professionals, patients, and regulatory authorities make informed decisions regarding the safe and rational use of medicines.

Based on the review of safety data, the Pharmacovigilance Programme of India (PvPI) has recommended the following signals (which is defined as information arising from one or multiple sources, including observations and experiments that suggests a new potentially causal association, or a new aspect of a known association, between an intervention and an adverse event or set of related adverse events, which is judged to be of sufficient likelihood to justify further investigation), prescribing information leaflet and issued drug safety alerts and communicated to stakeholders.

Signals identified by PvPI

S. No.	Suspected drugs	Adverse drug reactions
1.	Azithromycin	Fixed Drug Eruption
2.	Gliclazide	Erythema Multiforme

PvPI recommended the following Prescribing Information Leaflets changes/Summary of Product Characteristics

S. No.	Suspected drugs/vaccines	Adverse drug reactions
1.	Carbimazole	Agranulocytosis
2.	COVID-19 recombinant vaccine (ChAdOx1)	Guillain-Barré Syndrome
3.	Covaxin inactivated coronavirus (SARS-CoV-2) vaccine	Guillain-Barré Syndrome
4.	Doxycycline	CNS Side Effects (Restlessness, Anxiety, Irritability, Nervousness, Dizziness)
5.	Oxcarbazepine	DRESS Syndrome
6.	Tranexamic Acid	Back pain

Drug Safety Alerts issued by PvPI

S. No.	Suspected drugs	Adverse drug reactions
1.	Beta blockers (Metoprolol, Propranolol, Atenolol, Carvedilol)	Erectile Dysfunction (Reversible)
2.	Beta-blockers (Propranolol, Metoprolol)	Psoriasis
3.	Dalteparin	Muscle spasms
4.	Erythromycin	Fixed Drug Eruption
5.	Gliclazide	Erythema multiforme
6.	Luliconazole	Chloasma/Melasma
7.	Metoclopramide	Tachycardia
8.	Metronidazole	Acute Generalized Exanthematous Pustulosis
9.	Sulfamethoxazole + Trimethoprim	Leukopenia
10.	Tramadol	Fixed Drug Eruption
11.	Tranexamic Acid	Nasal Congestion

The above information is regularly updated by PvPI and uploaded on the web-portal of IPC i.e., https://www.ipc.gov.in

Strengthening patient safety through vigilance on ADRs and medication errors

Sangeeta Sharma,
Professor & Head, Neuropsychopharmacology,
Institute of Human Behaviour & Allied Sciences, Delhi

Medicines are powerful tools that improve survival, relieve suffering and control disease but they are not without risk. Harm may arise from adverse drug reactions (ADRs), which occur even when medicines are used correctly, or from medication errors, which are preventable and may happen during prescribing, dispensing, administration, or monitoring. Together, ADRs and medication errors remain major and often under-recognized threats to patient safety.

These issues extend beyond technical mishaps. They reflect how safely a health system delivers care. An ADR highlights that even appropriate medicine use can lead to unintended and serious harm. A medication error indicates a breakdown in the medication-use process, whether through the wrong drug, dose, patient, route, omitted therapy, or inadequate monitoring. One may be unavoidable; the other preventable; but both can cause patient injury, prolonged illness, increased costs, and loss of trust in healthcare.

As healthcare grows more complex, the challenge intensifies. Patients live longer with multiple chronic conditions requiring multiple medications. Care is provided across different settings and by various providers. High-alert medicines such as anticoagulants, insulin, antimicrobials, antiepileptics, and chemotherapeutic agents are used more frequently, raising the risk of medicine-related harm unless systems for safe use remain strong. This is especially relevant in India, where medicine use is vast and diverse across public and private sectors.

The impact extends beyond the individual. ADRs and medication errors can result in avoidable hospital admissions, prolonged stays, additional investigations, higher treatment costs, reduced adherence, and in severe cases, disability or death. They also strain already overburdened health systems. Therefore, medicine safety must be treated not only as a clinical concern but also as a public health and health-system priority.

Pharmacovigilance plays a crucial role in this effort. A robust pharmacovigilance system transforms individual reports into shared learning and preventive action. Reporting suspected ADRs helps detect new safety signals, identify vulnerable populations, and track evolving risks. Reporting medication errors, including near misses, exposes system gaps before more harm occurs. Each report contributes to safer practices and stronger evidence.

In India, the Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission (IPC) strengthens AE reporting, supports signal detection, builds awareness and reinforces a culture of medicine safety. Their work ensures pharmacovigilance becomes part of routine care rather than a separate task.

Ultimately, vigilance should be viewed as a professional ethics and a public health responsibility. When reporting becomes routine and learning is institutionalized, patient care becomes safer. The true measure of a health system lies not only in the medicines it provides but in how safely they are used.

Enrolment of New AMCs

NCC-PvPI, IPC has enrolled 30 new AMCs in 28th Phase of PvPI expansion. The total number of AMCs enrolled by the end of this quarter were 1150 across the country (Government:336 and Non-government:814). The list of newly enrolled AMCs is mentioned below:

S. No.	States/UTs	Name of Hospitals/Medical Colleges/Institutes	Status of Hospital (Government/ Non-Government)
1.	Andhra Pradesh	Anna Gowri Medical College & Hospital Parameswaramangalam, Puttur, Andhra Pradesh - 517584	Non-Government
2.		Mahathi College of Pharmacy CTM Cross Roads, Madanapalle, Mandal, Chittor, Annamayya, Andhra Pradesh - 517319	
3.	Assam	Diphu Medical College & Hospital Assam Karbi Anglong - 782462	Government
4.	Delhi	Santom Hospital CS/OCF4, Pkt. 10, Sector-24, Rohini, Delhi - 110033	Non-Government
5.	Haryana	Holy Help Hospital 5, Dabra Road, MDR 108, Model Town, Hisar, Haryana - 125011	Non-Goverment
6.		Chaudhary Orthopaedic & General Hospital D-5, Nandan Vatika, Sirsa, Haryana - 125055	
7.		Dhanvantari Multispeciality Hospital Jhunjhunu, Haryana - 333001	
8.		Om Multispeciality Hospital & Trauma Centre Karnal, Kaithal Road, Pundri, Haryana - 136026	
9.		Jangra Multispeciality Hospital Near New Bus Stand, Rohtak Road, Bhiwani, Haryana - 127021	

10.		Maharaja Hospital Near PNB Bank, Circular Road, Rewari, Haryana - 123401	
11.		Dr. Ram Narayan Soni Ortho Hospital & Trauma Center Sector 15 A, Kaimri Road, Hisar, Haryana - 125001	
12.		Lotus Diagnostic & Imaging Centre Near Gurudwara, Modal Town Hisar, Hissar City, Hisar, Haryana - 125001	
13.		Yatharth Super Speciality Hospital RPS City Sec 88, Faridabad - 121002	
14.	**Karnataka**	Hillside College of Pharmacy and Research Centre 9, Rahuvanahalli, Kanakapura Road, Bengaluru, Karnataka - 560062	Non-Government
15.	**Madhya Pradesh**	Akshaya Hospital 11, Link Road No 3, Rishi Nagar Bhopal, Madhya Pradesh - 462016	Non-Government
16.	**Maharashtra**	Lokmanya Hospital Sector-24, Tilka Road Pradhikaran, Nigdi, Pune, Maharashtra - 411044	Non-Government
17.		Seth Nandlal Dhoot Hospital Limites A-1 & A-2 MiDC, Chikal Thana, Jalna Road, Chh. Sambhaj Nagar, Maharashtra - 431210	
18.	**Punjab**	Behgal Institute of IT and Radiation Technology & Behgal Hospital SAS Nagar, Mohali, Punjab - 160071	Non-Government
19.		Atlantis Hospital, 5, City Enclame GT Road, Putlighar, Amritsar, Punjab - 143001	
20.		Shaheed Kartar Singh Sarabha Charitable Hospital, Sarabha, Ludhiana, Punjab - 141105	

ENROLMENT OF NEW AMCs

21.	**Rajasthan**	Puru Eye Hospital Opp. Dravyawati River Front Garden, Shipra Path, Mansarovar, Jaipur, Rajasthan - 302020	Non-Government
22.		Brijesh Banger Memorial Hospital Behind Ranjeev Gandhi Auditorium, RC Vyas colony Bhilwara, Rajasthan - 311001	
23.		Dr S.S. Tantia Medical College Hospital & Research Center, Tantia University Campus, Sriganganagar, Rajasthan - 335002	
24.		Shri KM Memorial Jain Heart and General Hospital, Sikar, Rajasthan - 332001	
25.		Vandana Memorial Hospital A-11, Hari Nagar, Vidhyadhar Nagar Road, Opp Jalsu House, Shashtri Nagar, Jaipur, Rajasthan - 302016	
26.	**Tamil Nadu**	G. P Pharmacy College Vaniyambadi Main Road Mandalavadi (Vill & PO), Jolarpettai, Tamil Nadu Tirupatthur -635851	Non-Government
27.	**Telangana**	Government Medical College Quthbuzlapur, North Kamla Nagar, Near Suvidha Hospital - Telangana - 500062	Government
28.		Goverment Medical College Rajanna Siacilla, Near Kashuba School, Telangana Rajanna - 505301	
29.	**Uttar Pradesh**	Hind Institute of Medical Sciences Barabanki, Uttar Pradesh - 225003	Non-Government
30.	**West Bengal**	Manipal Hospital Broadway JC-16 &17, Salt Lake City, Sector-3, Kolkata, West Bengal - 700106	Non-Government

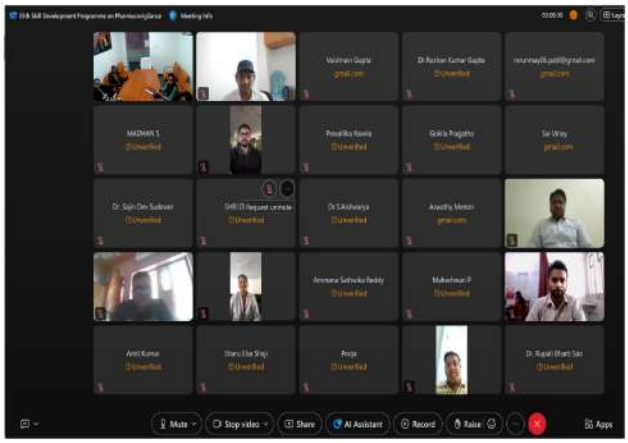
Workshop organized by SVIMS, Tirupati

Prof. K. Umamaheswara Rao, Coordinator, Dr. C. Pallavi, Deputy Coordinator, and Mrs. M.K. Manisha, Pharmacovigilance Associate, Department of Pharmacology, Sri Venkateswara Institute of Medical Sciences, Tirupati, Andhra Pradesh organized a workshop on 'Pharmacovigilance and Reporting of Adverse Drug Reactions' on 11th October 2025. Technical sessions included 'Pharmacovigilance Overview' by Dr. K. Umamaheswara Rao and 'Detection, Prevention, Management, and Reporting of Adverse Drug Reactions' by Mrs. M.K. Manisha along with hands on training. A total of 160 delegates participated in the workshop.

CME organised by KEM, Mumbai

Dr. Nithya Gogtay, Coordinator, Dr. Mahesh Belhekar, Deputy Coordinator and Ms. Pratiksha Thombare, Pharmacovigilance Associate at Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai organised Continuing Medical Education on the theme - 'CONSORT 2022 Harms Guideline' on 11th October 2025. Dr. Anjali Shah, IInd year DM Resident, Clinical Pharmacology, highlighted the need for detailed documentation of adverse events, including type, frequency, severity and attribution. Dr. Nithya Gogtay discussed the benefits of adherence for improving trial quality, participation safety, and research credibility. A total of 16 participants attended the event.

35th Skill Development Programme on Pharmacovigilance



The NCC-PvPI, IPC has conducted 35th Skill Development Programme (SDP) on Pharmacovigilance in virtual mode from 10th - 14th November 2025. In this SDP, a total of 19 technical sessions were conducted, starting with basic concepts and progressing to advanced signal detection and regulatory interventions by the subject experts from the pharmaceutical industries, academic and research Institutions. A total of 154 participants attended this training programme including industry professionals, physician, academicians, pharmacy students, medical students, and pharmacists across the country.

8th ALT organised by AIIMS, Bhopal

Dr. Ratinder Jhaj, Coordinator, Dr. Balakrishnan S, Deputy Coordinator and Ms. Deepa Chaudhary, Pharmacovigilance Associate at Department of Pharmacology, All India Institute of Medical Sciences, Bhopal, Madhya Pradesh organised ALT on the theme - 8th Advanced Level Training cum Coordinators meeting for Madhya Pradesh and Chhattisgarh on 14th November 2025. The Programme dealt with prime emphasis to sensitize all the coordinators, deputy coordinators and pharmacovigilance associates about recent updates in PvPI, AI in pharmacovigilance, Eco pharmacovigilance, patient safety, identification and management of cutaneous ADRs and case-based causality assessment activities. The programme also provided a common platform for coordinators, deputy coordinators and PvAs of different AMCs of Madhya Pradesh and Chhattisgarh to share their experiences and discuss ways to improve the spontaneous reporting of ADRs and AEFI. The Programme A total of 59 delegates participated in the programme.

CME organised by MMC, Chennai

Dr. K.M Sudha, Coordinator, Dr. S. Gomathi, Deputy coordinator and Ms. Siddiraju Devipriya, PvA at Institute of Pharmacology, Madras Medical College, Chennai organised CME on the theme- 'Pharmacovigilance - Ensuring Patient Safety Through Multidisciplinary Monitoring and Reporting' on 14th November 2025. Dr. Vijit Agrawal, Sr. PvA, NCC-PvPI, IPC highlighted on current updates of PvPI with an emphasis on status of ADR reporting in India. Dr. KM Sudha enlightened on the essential documents including sADR reporting form, consumer reporting form, ICSR, PSUR, PBRER, PADER and PASS under Pharmacovigilance. Other expert session focused on different topics of pharmacovigilance such as antitubercular treatment, safety monitoring in Psychiatry practice, drug-drug Interactions. A total of 256 delegates participated in the CME.

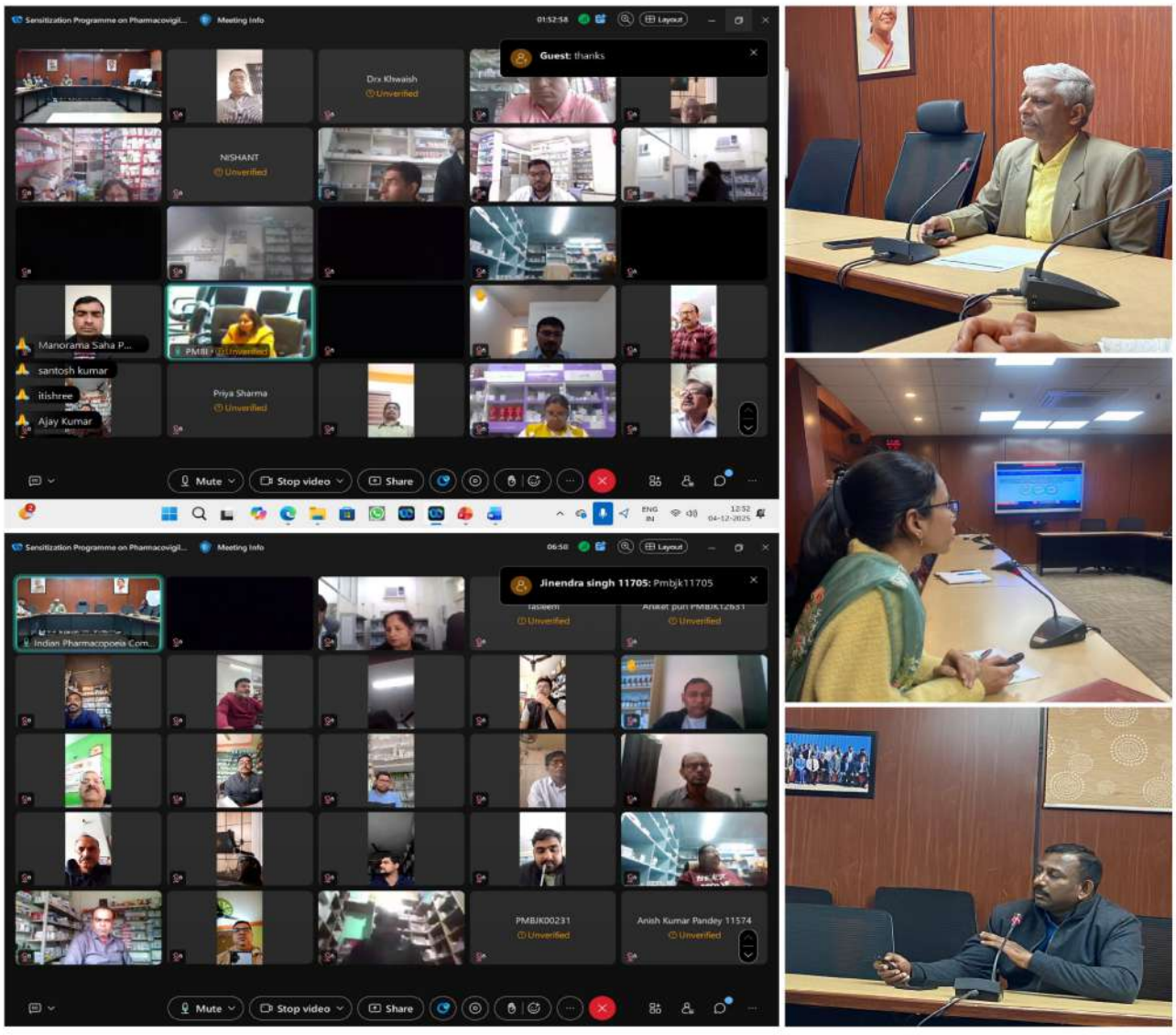
CME organised by AJIMS, Mangalore

Dr. Sharatha Kumar Coordinator, Dr. Srinivas Bhat Deputy Coordinator, Dr. Dencita Merlyn Dsouza, PvA organised CME on Pharmacovigilance - Safeguarding Patient Health on 4th December 2025 at A. J. Institute of Medical Sciences and Research Centre, Mangalore. The session covered concept of Pharmacovigilance and emphasized its vital role in ensuring patient safety highlighting the global benefits and impact of pharmacovigilance in monitoring drug safety and preventing adverse outcomes, current trends and recent developments in pharmacovigilance, including evolving regulatory practices and technological advancements, while underlining why pharmacovigilance is an essential component of modern healthcare systems. A total of 192 participants attended the session.

TRAINING & EDUCATION

Sensitization programme on pharmacovigilance for pharmacists of Jan Aushadhi Stores

The Pharmacists working at Jan Aushadhi Stores play an important role as they directly interact with patients and dispense affordable generic medicines under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP). To enhance their awareness and capacity building in identifying and reporting ADRs, the NCC-PvPI conducted Sensitization programme on the pharmacovigilance was conducted on 4th December 2025. Dr. Jai Prakash, Officer-in-Charge, PvPI, addressed participants, thanked the PMBI team, and explained the structure of the Pharmacovigilance Programme of India, highlighting the role of pharmacists in ADR reporting. Dr. R.S. Ray discussed ADR reporting tools, followed by a hands-on ADRMS demonstration by Dr. Mahima Maheshwari. The interactive session improved understanding of ADR/AE reporting and concluded with appreciation for the PvPI team. A total of 1650 participants attended the programme.



ALT organized by IPGMER, Kolkata

Dr. Suparna Chatterjee, Coordinator, Dr. Avijit Hazra, Deputy Coordinator, Md. Babu Gazi Pharmacovigilance Associate, Institute of Postgraduate Medical Education & Research, Kolkata organised East Zone Regional Advance Level Training program on the theme 'Proactive Monitoring for a safer TB Cure' on 10th December 2025. The scientific sessions began with 'An Update about PvPI' by Dr. Jai Prakash, Senior Scientific Officer, NCC-PvPI, IPC, Ghaziabad who gave a comprehensive overview of PvPI activities, reporting trends, signal generation" and the importance of regional ADR contributions. The session focused on tuberculosis management and drug safety, covering treatment roadmaps for drug-sensitive and drug-resistant TB, adverse effects of antitubercular drugs, liver injury, TB-HIV co-infection, BCG vaccine adverse events, and paediatric safety challenges. Emphasis was placed on monitoring, early detection, reporting, and clinical management. A total of 210 participants joined the program.

Sensitization and basic training workshop in GMERSMC, Ahmedabad

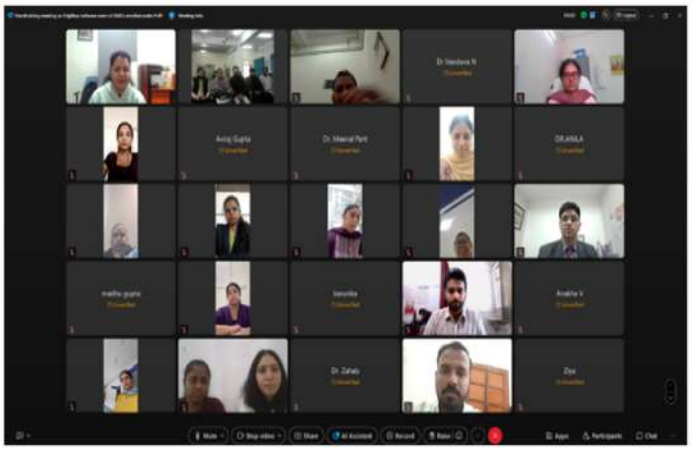
Dr. Mukeshkumar B. Vora, Coordinator, Dr. Krina Patel, Deputy Coordinator and Dr. Payal M. Patel, Pharmacovigilance Associate, organised Sensitization and basic training workshop in Pharmacovigilance on 10th-12th December 2025. The training commenced with an interactive introduction to Pharmacovigilance and the Pharmacovigilance Programme of India. Sessions included ADR reporting, hands-on group activities, artificial intelligence applications, consumer and non-prescriber reporting, improving detection practices, and causality assessment. A total of 18 delegates participated in the programme.

ALT organised by GMC, Guwahati

Dr. Bhaskar Jyoti Dutta, Coordinator, Dr. Ripunjoy Sannah, Deputy Coordinator, Debasish Saloi, Pharmacovigilance Associate, Government Medical College and Hospital, Guwahati organised North East Pharmacovigilance ALT 2025 on 16th December 2025. The session provided an overview of pharmacovigilance and PvPI, highlighting drug safety issues in elderly patients. It focused on identification, reporting, causality assessment, and analysis of adverse drug reactions, complemented by hands-on training using real hospital cases, and emphasized the crucial role of healthcare professionals in ensuring patient safety. A total number of 110 Participants attended the event.

Handholding meeting on VigiFlow software

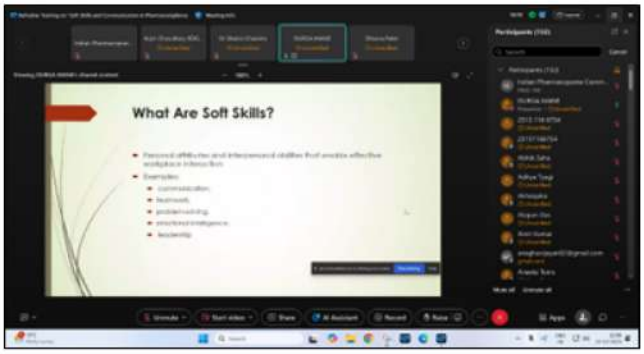
Handholding meeting on users of AMCs enrolled under PvPI including Coordinators, Deputy-Coordinators & Junior Pharmacovigilance Associates of NCC & ADR monitoring Centres across the country was conducted on 19th December 2025. The session described entering the ICSRs into the VigiFlow software and resolved the queries of attendees regarding VigiFlow processing. Total number of participants were 140.



CME organised by KEM Hospital, Mumbai

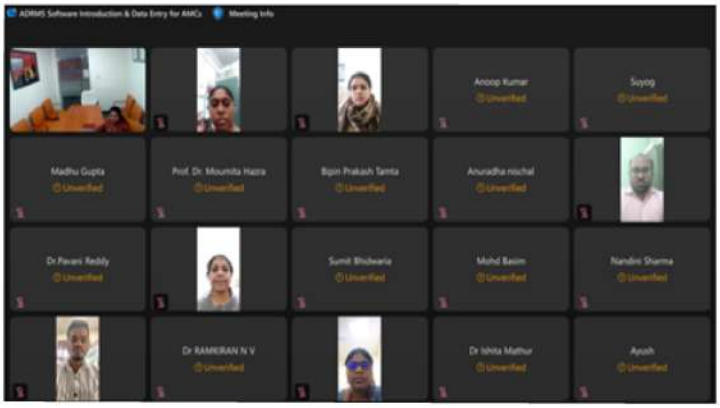
Dr. Nithya Gogtay, Coordinator, Dr. Mahesh Belhekar, Deputy Coordinator and Ms. Pratiksha Thombare, Pharmacovigilance Associate conducted CME on ADR Reporting at Department of pharmacology, Seth GS Medical College & KEM Hospital, Mumbai on 19th December 2025. The session began with an interactive discussion on Adverse Drug Reactions, highlighting their importance in clinical practice. Real-life examples, ADR classification, reporting processes, and roles of healthcare professionals were discussed. The session emphasized systematic reporting, patient safety, and concluded with an engaging Q&A promoting a strong pharmacovigilance culture. A total number of 251 Participants attended the event.

Training on soft skills & communication in pharmacovigilance



Training on 'Soft Skills & communication in Pharmacovigilance' was organised on 22nd December 2025 by NCC, IPC, Ghaziabad in which Dr. Durga Mane addressed the audience about the importance of soft skills in Pharmacovigilance. She discussed some interesting topics like human side of drug safety, communication under pressure and strategies to strengthen soft skills. The session highlighted that soft skills account for 85% of career success, surpassing technical skills in importance. Soft skills and communication are essential for meaningful patient safety outcomes in pharmacovigilance. The participants also interacted with Dr. Durga and she answered all the queries. The training program ended with participants expressing thanks to PvPI team for organising the training. A total of 159 participants attended the programme.

Training on ADRMS software



Training session was conducted on ADRMS Software- Introduction & Data Entry for AMCs enrolled under PvPI including Coordinators, Deputy-Coordinators & Pharmacovigilance Associates of NCC & ADR monitoring Centres across the country on 30th December 2025. The session described entering the ICSRs into the ADRMS software and resolved the queries of attendees regarding ADRMS software processing. A total number of 53 participants attended the training session.

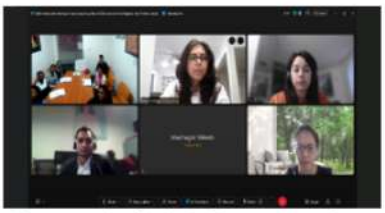
Interactive meetings with Marketing Authorization Holders

The objective of Interactive meetings is to review the quality, number of ICSRs received in a calendar year, and completeness score of ICSRs received from Marketing Authorization Holders (MAHs) and inform the same to representatives of MAHs for taking improvement measures. The details of such Interactive meetings held virtually with MAHs are as follows:

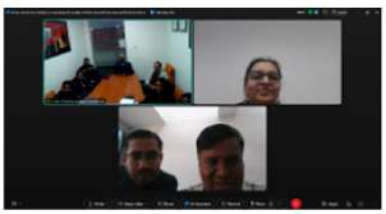
S. No.	Date	Marketing Authorization Holders	No. of Representatives
1.	16th October 2025	Intas Pharmaceuticals Limited	15
2.	26th November 2025	Organon India Limited	12
3.	23rd December 2025	Fresenius Kabi Oncology Limited	13
4.	30th December 2025	Exemed Pharmaceuticals	12

Intas Pharmaceuticals Ltd. Representatives

Fresenius Kabi Oncology Ltd. Representatives



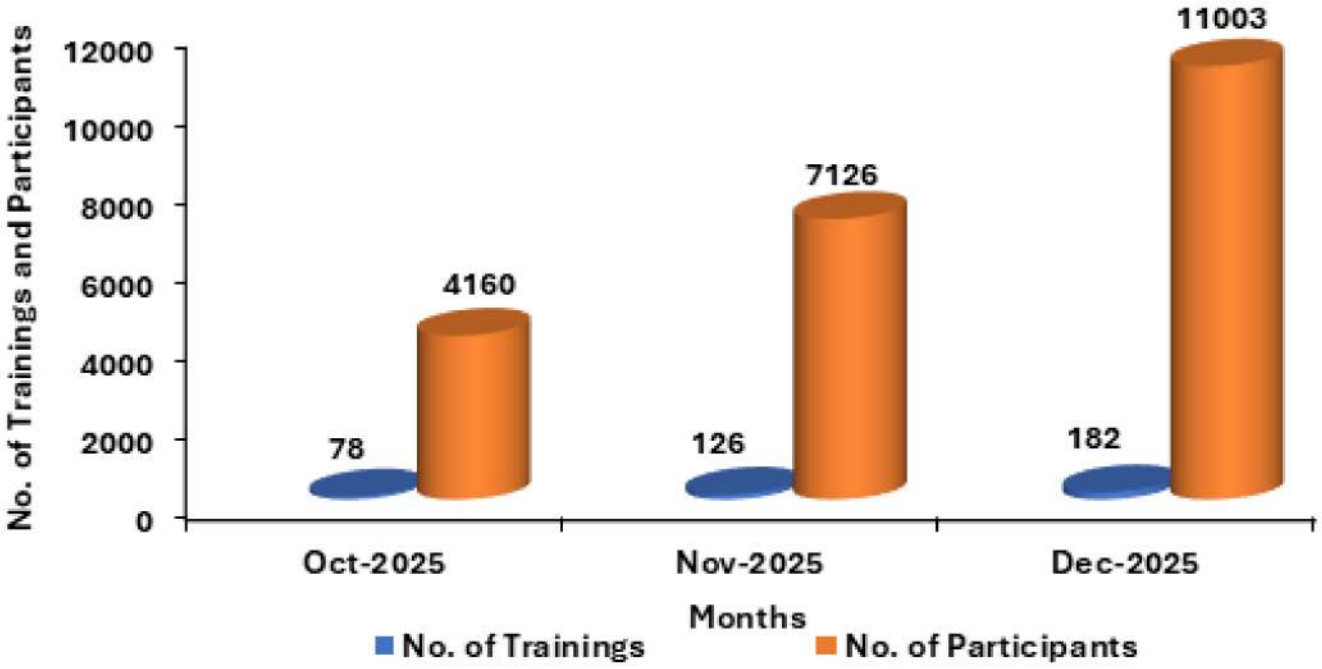
Organon India Ltd. Representatives



Exemed Pharmaceuticals Representative

Monthly trends of training programmes conducted by PvPI

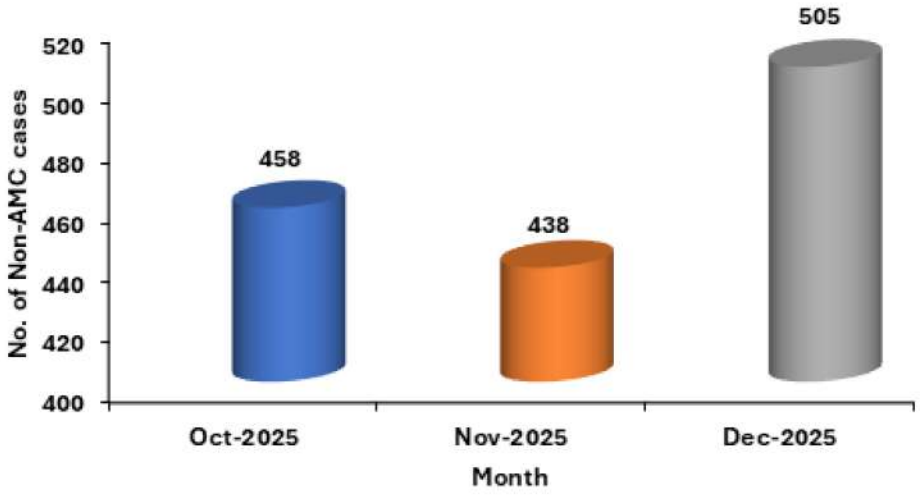
The NCC-PvPI, IPC organised a total of 386 training programmes including Skill Development Programmes, Continuing Medical Education, Advanced Level Training Programmes etc. and trained a total number of 22289 participants in the area of Pharmacovigilance across the country.



Monthly trends of training programmes

Monthly trends of Non-AMC cases received at PvPI

The NCC-PvPI, IPC received a total of 1401 cases from Non-AMCs from across the country.



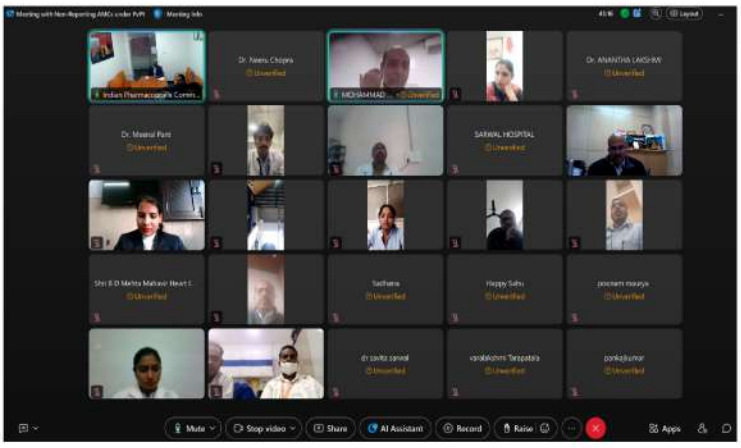
Monthly trends of Non-AMC cases

QUALITY REVIEW PANEL

11th Quality Review Pannel (QRP) meeting

The 11th Quality Review Pannel (QRP) meeting was conducted on 9th December 2025 at IPC, Ghaziabad in hybrid mode. Dr. Jai Prakash, the member secretary, QRP welcomed all the members and presented the agenda before the Panel. Prof. H S Rehan, Chairman QRP, in his opening remarks emphasized to identify the current challenges to the PvPI and devise their mitigation strategies. During the meeting, key issues related to the functioning and improvement of PvPI activities were discussed in detail, and the recommendations provided by the members of the QRP were noted for further necessary action.

Meeting with AMCs to strengthen ADR reporting under PvPI



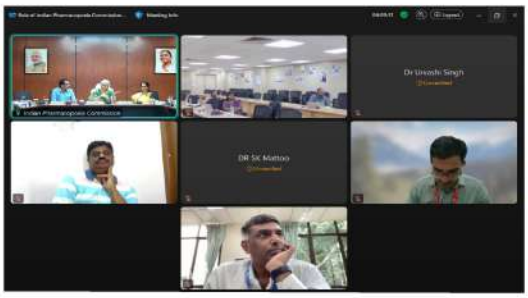
A virtual meeting with Coordinators and Deputy Coordinators of Adverse Drug Reaction Monitoring Centres (AMCs) under the PvPI was conducted on 23rd December 2025. Dr. Jai Prakash, Sr. PSO and Officer-in-Charge, welcomed the participants and presented the current status of PvPI following a brief introduction of attendees. During the interaction, AMC representatives shared operational challenges affecting ADR reporting, and possible solutions were discussed to strengthen reporting practices. Dr. Jai Prakash encouraged active participation in training programmes organized by NCC-PvPI and emphasized the importance of regular ADR reporting for sustaining AMC status. He also informed participants about the ongoing update of the National Formulary of India and invited suggestions to promote safer use of medicines.

Participation of PvPI Representatives in different meetings

A sensitization workshop in National Leprosy Eradication Programme

A Sensitization Workshop in National Leprosy Eradication Programme for District Leprosy Officers (DLOs) to establish a Pharmacovigilance System for Adverse Events' Reporting was jointly organized by Central Leprosy Division, Ministry of Health and Family Welfare, in collaboration with WHO India country office and the Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission at The Leprosy Mission Trust India-Diana Princess of Wales Health Education and Media Centre, Noida, Uttar Pradesh on 14th October 2025. Dr. RS Ray, Scientific Assistant, Dr. Vijit Agrawal, Sr. Pv Associate, Dr. Jaishree Sures, Jr. PvA, Dr. Divyansh, Jr. MvA had attended this workshop from IPC. Dr. Vijit Agrawal, Sr. Pv Associate, NCC-PvPI, IPC was nominated to attend this event as a speaker to deliver a talk on the topic 'Linking District Leprosy Units to ADR Monitoring Centres for Effective Drug Safety Reporting- How to fill Suspected ADR reporting form for Leprosy Medicines'.

TB elimination meeting at IPC



A meeting was organized titled “Promoting the Quality, Safety and Rational Use of Anti-TB Drugs – Current status and way forward in TB Elimination” on 30th October 2025 in hybrid mode at RS Iyer Hall, IPC, Ghaziabad. This meeting was chaired by Dr. Soumya Swaminathan, Ex-Chief Scientist at the WHO, Geneva Switzerland & Ex- Director General, Indian Council of Medical Research, New Delhi, India. The IPC staff and representatives from Central TB Division, CDSCO had attended this meeting. The IPC division heads had moderated and shared the working strategies with the chair and she advised IPC on how we can improve in terms of Promoting the Quality, Safety and Rational Use of Anti-TB Drugs.

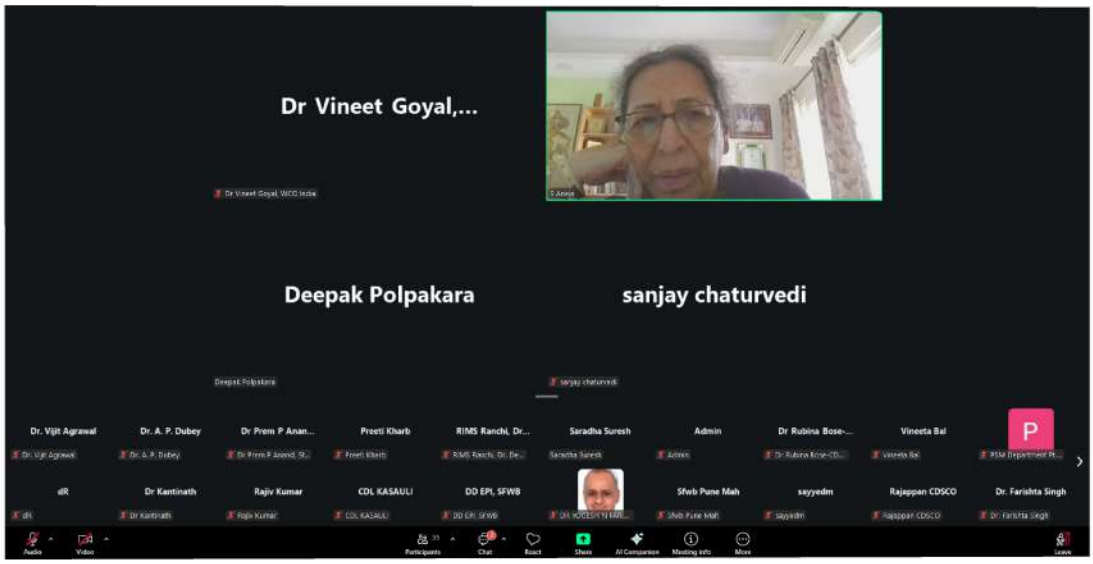
PvPi Participation

55th Annual National Conference of the Indian Pharmacological Society

Indian Pharmacopoeia Commission (IPC), Ghaziabad, organized a scientific symposium titled "Vigilance of Medical Products" during the 55th Annual National Conference of the Indian Pharmacological Society (IPC IPSCON 2025) held at Panjab University, Chandigarh, on 22nd November 2025. The session was chaired by Dr. Jai Prakash, Officer-in-Charge, NCC-PvPI, IPC, and co-chaired by Prof. Bikash Medhi, PGIMER, Chandigarh. Expert talks were delivered by Dr. Shashi Bhushan, Prof. Bikash Medhi, Dr. Shivani Juneja Bedi, and Naveen Veerasekaran, highlighting the role of pharmacovigilance and materiovigilance in strengthening patient safety and monitoring of medicines and medical devices in India.

National AEFI committee meeting

The National AEFI Committee meeting was held on 16th and 19th December 2025 over the video conferencing. This meeting was aimed to approve the causality assessment classification of the AEFI cases reported following the paediatric and adult vaccinations. Dr. Vijit Agrawal Sr Pv Associate, IPC had attended this meeting virtually. Approx 35 participants had attended this meeting.



New drugs approved in India

The following new drugs were approved by the CDSCO during this index period;

S. No.	New Drugs	Approved Indication(s)	Date
1.	Erdafitinib Tablets 3 mg, 4 mg and 5 mg	Indicated for the treatment of adult patients with locally advanced or metastatic-Urothelial Carcinoma (mUC) with susceptible FGFR3 (Fibroblast Growth Factor Receptor 3) genetic alterations whose disease has progressed on or after at least one line of prior systemic therapy. Limitations of Use: Erdafitinib is not recommended for the treatment of patients who are eligible for and have not received prior PD-1 (Programmed Cell Death Protein 1) or PD-L1 (Programmed Death-Ligand 1) inhibitor therapy.	1st October 2025
2.	Erdafitinib Bulk Drug	Not applicable as it is a bulk drug	8th October 2025
3.	Vorasidenib Tablets 10 mg/ 40 mg	Vorasidenib is indicated for the treatment of adult and paediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation following surgery including biopsy, subtotal resection, or gross total resection.	15th October 2025

Source

cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM1NTA= *(accessed on 31st December 2025)*

☞ Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of ADR associated with the use of above new drugs. If any reaction is encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form for HCP/Medicines Side Effect Reporting Form for Consumer available at https://www.ipc.gov.in and PvPI Helpline Number. 1800-180-3024.

REGULATORY MATTERS

Notification regarding Nimesulide

रजिस्ट्री सं. डी.एल.- 33004/99 REGD. No. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

सी.जी.-डी.एल.-अ.-30122025-268922
CG-DL-E-30122025-268922

असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (ii)
PART II—Section 3—Sub-section (ii)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 5891] नई दिल्ली, मंगलवार, दिसम्बर 30, 2025/पौष 9, 1947
No. 5891] NEW DELHI, TUESDAY, DECEMBER 30, 2025/PAUSHA 9, 1947

स्वास्थ्य और परिवार कल्याण मंत्रालय

(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 29 दिसम्बर, 2025

का.आ. 6091(अ).—केन्द्रीय सरकार इस बात से संतुष्ट है कि 100 मिलीग्राम से ज़्यादा निमेसुलाइड वाले सभी ओरल फ़ॉर्मूलेशन का इस्तेमाल इंसानों के लिए खतरनाक हो सकता है और इस दवा के सुरक्षित विकल्प उपलब्ध हैं;

और, केन्द्रीय सरकार इस बात से संतुष्ट है कि लोगों के हित में देश में इंसानों के इस्तेमाल के लिए इस दवा के निर्माण, बिक्री और वितरण पर रोक लगाना आवश्यक और उचित है;

अतः, अब, केन्द्रीय सरकार, औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 26क द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए और औषधि तकनीकी सलाहकार बोर्ड से परामर्श के पश्चात, निम्नलिखित दवा के निर्माण, बिक्री और वितरण पर तत्काल प्रभाव से, रोक लगाती है, जो इस प्रकार है: –

"सभी ओरल फ़ॉर्मूलेशन जिनमें इमीडिएट रिलीज़ डोज़ेज फ़ॉर्म में 100 मिलीग्राम से ज़्यादा निमेसुलाइड होता है।"

[फा.सं. एक्स.11035/100/2024-डीआरएस]

हर्ष मंगला, संयुक्त सचिव

8807 GI/2025 (1)

2 THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(ii)]

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 29th December, 2025

S.O. 6091(E).—Whereas the Central Government is satisfied that the use of all oral formulations containing Nimesulide above 100 mg in immediate release dosage form are likely to involve risk to human beings and that safer alternatives to the said drug is available;

And, whereas, the Central Government is satisfied that it is necessary and expedient in the public interest to prohibit the manufacture, sale and distribution of the said drug in the country for human use;

Now, therefore, in exercise of the powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), and after consultation with the Drugs Technical Advisory Board, the Central Government, hereby prohibits the manufacture, sale and distribution of the following drug, with immediate effect, namely:-

"All oral formulations containing Nimesulide above 100 mg in immediate release dosage form."

[F. No. X.11035/100/2024-DRS]

HARSH MANGLA, Jt. Secy.

Press & Media

World Health Organization

WHO pharmaceuticals NEWSLETTER

2025 No.3

COVID-19 whole virion, inactivated vaccine

Risk of Guillain-Barré syndrome

India. The Signal Review Panel for Vaccines has made a recommendation to the CDSCO on inclusion of Guillain-Barré syndrome as an adverse event with unknown frequency in the product information of whole virion, inactivated coronavirus (SARS-CoV-2) vaccine (Covaxin®) based on the evaluation of data reported in Adverse Event Following Immunization (AEFI) surveillance database and published literature.

The CDSCO has issued a letter to the concerned manufacturer to update the product information as per the recommendation.

Reference:
Based on the communication from IPC, India, January 2025 and letter in February 2023 (link to the source within ipc.gov.in)

COVID-19 recombinant vaccine (ChAdOx1)

Risks of Guillain-Barré syndrome and facial paralysis

India. The Signal Review Panel for Vaccines under Immunization Division of Ministry of Health & Family Welfare, Government of India has made a recommendation to the Central Drugs Standard Control Organization (CDSCO) on the inclusion of Guillain-Barré syndrome as a very rare adverse event as well as facial paralysis as a rare adverse event in the product information of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) (Covishield®) based on the evaluation of AEFI related data, published medical literature and recommendation of Pharmacovigilance Programme of India (PvPI).

The CDSCO has issued a letter to the concerned manufacturer to update the product information as per the recommendation.

Reference:
Based on the communication from Indian Pharmacopoeia Commission (IPC), India, January 2025 and letter in February 2023
(See also WHO pharmaceuticals newsletter No.4, 2021: ChAdOx1 nCoV-19 and risk of Guillain-Barre syndrome in Europe)

Source: *https://www.who.int/publications/b/81054*

Ministry of Health and Family Welfare

Azadi Ka Amrit Mahotsav

India Joins Global #MedSafetyWeek Campaign to Promote Safe Use of Medicines

India Reiterates Commitment to Patient Safety through Global #MedSafetyWeek 2025 Campaign

#MedSafetyWeek 2025 records Global Participation Across 117 Countries and 130 Organisations

Posted On: 10 NOV 2025 5:54PM by PIB Delhi

Source: *https://www.pib.gov.in/PressReleasePage.aspx?PRID=2188441&reg=3&lang=2*

PRESS & MEDIA

PHARMABIZ.com

IPC leads 2025 10th #MedSafetyWeek Campaign in India to raise awareness on ADRs

Shardul Nautiyal, Mumbai
Wednesday, November 12, 2025, 08:00 Hrs [IST]

The National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) participated in the 2025 Tenth #MedSafetyWeek Campaign between 03 and 09 November 2025 to raise awareness on suspected side effects from medicines or adverse drug reactions (ADRs). The IPC is one of 130 partner organisations globally which took part in this campaign.

Medicines save lives and improve the health of millions of people globally. Sometimes they can also cause unintended side effects. By reporting suspected side effects when they do occur, regulators can act to make medicines safer.

The 2025 Tenth Anniversary Edition is the largest so far, with 130 organisations in 117 countries committed to sharing the #MedSafetyWeek message in more than 60 languages. With this campaign, India through the IPC joined the 10th Anniversary Campaign for safer use of medicines. The #MedSafetyWeek Campaign was founded in 2016 to raise awareness of why, how, and where to report side effects.

#MedSafetyWeek is an international campaign led by Uppsala Monitoring Centre (UMC), the World Health Organization (WHO) Collaborating Centre for International Drug Monitoring. The campaign is supported by WHO, members of the International Coalition of Medicines

Source: *https://www.pharmabiz.com/NewsDetails.aspx?aid=182369&sid=1*

Scan to report side effects: Govt orders mandatory QR codes at all pharmacies

Anuja Jaiswal / TNN / Dec 03, 2025, 23:22 IST

Share AA Select TOI as

Pharmacies across India will soon feature a QR code and toll-free number to report medicine side effects. This initiative by the CDSCO aims to empower citizens and healthcare professionals to instantly flag adverse drug reactions, strengthening India's drug safety monitoring. The move is expected to significantly boost ... Read More

NEW DELHI: The next time you step into a chemist shop, you may find a new addition near the counter — a black-and-white QR code that could quietly transform India's drug safety system. The Central Drugs Standard Control Organisation (CDSCO) has directed every retail and wholesale pharmacy in the country to display the official Pharmacovigilance Programme of India (PvPI) QR code along with its toll-free number, 1800-180-3024, enabling people to report medicine side effects instantly.

Source: *https://timesofindia.indiatimes.com/india/scan-to-report-side-effects-govt-orders-mandatory-qr-codes-at-all-pharmacies/articleshow/125749587.cms*

THE ECONOMIC TIMES

CDSCO directs pharmacies to display QR code and toll-free number for reporting adverse drug

The Central Drugs Standard Control Organisation (CDSCO) has instructed drug licensing authorities across all states and Union Territories to ensure that every retail and wholesale pharmacy prominently displays a designated Quick Response (QR) code and a toll-free number to enable the reporting of adverse drug reactions.

According to the CDSCO, this initiative aims to streamline and improve the process for the public and healthcare professionals to report adverse events through the PvPI Adverse Drug Reaction Monitoring System, developed in India.

The directive was issued following the 16th Working Group Meeting of the Pharmacovigilance Programme of India, held on June 18.

Source: *https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/cdsco-directs-pharmacies-to-display-qr-code-and-toll-free-number-for-reporting-adverse-drug-reactions/articleshow/125745752.cms*

THE TIMES OF INDIA

Chemists across India will soon have new QR Code and toll-free number, here's what it will mean for buyers

TOI Tech Desk / TIMESOFINDIA.COM / Dec 04, 2025, 11:11 IST

Drug licensing authorities nationwide are now mandated to display a Quick Response (QR) code and toll-free number at all pharmacies. This initiative, driven by the CDSCO, aims to simplify the reporting of adverse drug reactions by the public and healthcare professionals directly into the PvPI Adverse Drug Reaction Mc ...Read More

Government has a new mandate for chemists across the country. The Central Drugs Standard Control Organisation (CDSO) has directed drug licensing authorities in all states and Union territories across India to ensure that a designated Quick Response (QR) code and toll-free number are displayed at all retail and wholesale pharmacies. This QR Code and Toll-free number is aimed to help people report side-effects of medicines. This measure will facilitate seamless reporting of adverse events and adverse drug reactions by the public and healthcare professionals through the indigenous PvPI Adverse Drug Reaction Monitoring System, the CDSCO said. The decision was taken during the 16th Working Group Meeting of the Pharmacovigilance Programme of India in June this year. Senior officials see this as a major shift in how India tracks harmful drug events, which often go unreported.

Source: *https://timesofindia.indiatimes.com/technology/tech-news/chemists-across-india-will-soon-have-new-qr-code-and-toll-free-number-heres-what-it-will-mean-for-buyers/articleshow/125759061.cms*

Patient/Consumer Feedback on PvPI

I have been taking treatment at Karpagam hospital, Coimbatore for past few years. At the time of dispensing drugs, patients are informed about the drug side-effects. Due to this education about reporting drug side effects, I am aware of reporting it through toll free number to the pharmacovigilance program of India.

Mrs. Venilla
Coimbatore
Tamil Nadu

As worker at NIMS-Hyderabad, I have direct access to the clinical pharmacology department of NIMS which made me aware of Pharmacovigilance Programme of India. I do sometimes ask doubts and get counselling from residents in the department. This also made me aware of side effects of few medicines as I and my husband are taking medicines for diabetes and hypertension..

S. Shobha Rani
Uppuguda,
Hyderabad, Telangana

Forthcoming Events

S. No.	Date	Title	Who can participate?
1.	14th January 2026	Induction-cum-Training Programme on Pharmacovigilance	• Coordinators • Deputy Coordinators • PV Associates at AMCs and NCC
2.	27th January 2026	Refresher training on Signal detection in Pharmacovigilance	• Coordinators • Deputy Coordinators • PV Associates at AMCs and NCC
3.	27th - 28th February 2026	1st Annual Meet for AMCs & MDMCs of PvPI and MvPI	• Coordinators • Deputy Coordinators • PV & MV Associates
4.	9th-13th March, 2026	36th Skill Development Programme at NCC-PvPI, IPC (Virtual)	• Healthcare Professionals • Pharmacovigilance Professionals • Medical/Para-medical/Pharmacy Students • Pharmacists • Academicians
5.	25thMarch, 2026	Induction-cum-training programme for newly recognized AMCs and new Pharmacovigilance Associates	• Coordinators • Deputy Coordinators • PV Associates at AMCs and NCC

दवाइयों से होने वाले प्रतिकूल/दुष्प्रभाव की निगरानी एवं मरीजों की सुरक्षा के प्रति जागरूकता

फार्माकोविजिलैंस प्रोग्राम ऑफ़ इंडिया, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार द्वारा जनहित में जारी

औषधि सतर्कता कार्यक्रम (फार्माकोविजिलैंस प्रोग्राम ऑफ़ इंडिया) क्या है?

फार्माकोविजिलैंस प्रोग्राम ऑफ़ इंडिया, स्वास्थ्य एवं परिवार कल्याण मंत्रालय के अंतर्गत कार्य करता है जिसका नोडल कार्यालय, भारतीय भेषज संहिता आयोग में स्थित है। मैटीरियोविजिलैंस प्रोग्राम ऑफ़ इंडिया जिसका नोडल कार्यालय भी भारतीय भेषज संहिता आयोग में स्थित है तथा हीमोविजिलैंस प्रोग्राम ऑफ़ इंडिया जिसका नोडल कार्यालय राष्ट्रीय जैविक संस्थान, नॉएडा में स्थित है, वे भी इसी के भाग हैं।

उद्देश्य

राष्ट्रीय औषधि सतर्कता सप्ताह का उद्देश्य औषधियों से होने वाले दुष्प्रभाव के प्रति जागरूकता फैलाना व इनसे होने वाले दुष्प्रभावों को फार्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया को रिपोर्ट करना है।

औषधि सतर्कता क्या है?

सामान्य मात्रा में किसी औषधि अथवा दवा का सेवन करने से होने वाले प्रतिकूल प्रभाव अथवा दुष्प्रभाव का पता लगाने, उसका मूल्यांकन करने, समझने व रोकथाम से सम्बंधित विज्ञान एवं गतिविधियों को औषधि सतर्कता विज्ञान कहते हैं तथा इस विषय में सजग/ सतर्क रहने को औषधि सतर्कता कहते हैं।

दवा प्रतिक्रिया/ एडवर्स ड्रग रिएक्शन (एडीआर)

औषधियों का वह प्रभाव जो हानिकारक और अनअपेक्षित है और जो आमतौर पर मनुष्यों में बीमारी की रोकथाम, निदान या उपचार के लिए या शारीरिक कार्य के संशोधन के लिए उपयोग की जाने वाली खुराक पर होती है, को दवा प्रतिक्रिया/ एडवर्स ड्रग रिएक्शन कहते हैं।

औषधि दुष्प्रभावों को कौन रिपोर्ट कर सकता है?

सभी स्वास्थ्य कर्मचारी (चिकित्सक, दंत चिकित्सक, फार्मासिस्ट, नर्स और उपभोक्ताओं सहित गैर-स्वास्थ्य देखभाल कर्मचारी) दवाओं के दुष्प्रभाव को रिपोर्ट कर सकते हैं।

औषधि दुष्प्रभावों को रिपोर्ट क्यों करें?

स्वास्थ्य कर्मचारी के रूप में सार्वजनिक स्वास्थ्य की सुरक्षा के लिए औषधि उत्पादों से जुड़े प्रतिकूल प्रभावों को रिपोर्ट करना एक नैतिक जिम्मेदारी है।

क्या रिपोर्ट करें?

औषधियों से होने वाले किसी भी प्रकार की प्रतिक्रियाएं भले ही ज्ञात हों या अज्ञात, गंभीर हों या अगंभीर, अक्सर हो या दुर्लभ, ऐसी सभी प्रतिक्रियाओं की रिपोर्टिंग कर सकते हैं।

कैसे और किसे रिपोर्ट करें?

1. हेल्पलाइन नंबर 1800-180-3024 पर कॉल करके (सोमवार से शुक्रवार सुबह 9:00 बजे से सायं 5:30 बजे)।
2. हमारी वेबसाइट www.ipc.gov.in पर औषधि दुष्प्रभाव सूचना फॉर्म डाउनलोड करके व उचित तरीकें से भरकर ई-मेल करें।
3. हमारी ई-मेल आई डी है pvpi.ipc@gov.in, pvpi.compat@gmail.com
4. यह सुविधा गूगल प्ले स्टोर पर मुफ्त उपलब्ध है।
5. आप "ADR PvPI" App डाउनलोड कर सकते हैं।

कोविड-१९ महामारी के दौरान उपयोग होने वाली औषधियों से होने वाले दुष्प्रभाव की जानकारी कहाँ और कैसे दें

इसकी जानकारी आप फॉर्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया के अंतर्गत किसी भी निकटवर्ती ऐ॰ डी॰ आर॰ मॉनिटरिंग सेंटर पर दे सकते हैं। इस सम्बन्ध में एक विशेष फॉर्म - Suspected Adverse Drug Reaction Reporting Form (For Drugs used in Prophylaxis/ Treatment of COVID-19) भी डिज़ाइन किया गया है, जो www.ipc.gov.in पर उपलब्ध है ।

सत्यमेव जयते
IPC

Indian Pharmacopoeia Commission
National Coordination Centre,
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare, Govt. of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392

For any other information/Suggestion/ Query, please contact:
Officer-in-Charge
Pharmacovigilance Programme of India
Email: lab.ipc@gov.in, pvpi.ipc@gov.in
Website: www.ipc.gov.in

Let us join hands with PvPI to ensure patient safety